

IN THE UNITED STATES DISTRICT COURT  
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

IN RE: DIET DRUGS (PHENTERMINE/  
FENFLURAMINE/DEXFENFLURAMINE)  
PRODUCTS LIABILITY LITIGATION

MDL NO. 1203

THIS DOCUMENT RELATES TO:

SHEILA BROWN, et al.

v.

CIVIL ACTION NO. 99-20593

AMERICAN HOME PRODUCTS  
CORPORATION

2:16 MD 1203

MEMORANDUM IN SUPPORT OF SEPARATE PRETRIAL ORDER NO.

Bartle, J.

June 5, 2013

Tamara Glaser ("Ms. Glaser" or "claimant"), a class member under the Diet Drug Nationwide Class Action Settlement Agreement ("Settlement Agreement") with Wyeth,<sup>1</sup> seeks benefits from the AHP Settlement Trust ("Trust"). Based on the record developed in the show cause process, we must determine whether claimant has demonstrated a reasonable medical basis to support her claim for Matrix Compensation Benefits ("Matrix Benefits").<sup>2</sup>

1. Prior to March 11, 2002, Wyeth was known as American Home Products Corporation. In 2009, Pfizer, Inc. acquired Wyeth.

2. Matrix Benefits are paid according to two benefit matrices (Matrix "A" and Matrix "B"), which generally classify claimants for compensation purposes based upon the severity of their medical conditions, their ages when they are diagnosed, and the presence of other medical conditions that also may have caused or contributed to a claimant's valvular heart disease ("VHD"). See Settlement Agreement §§ IV.B.2.b. & IV.B.2.d.(1)-(2). Matrix A-1 describes the compensation available to Diet Drug Recipients with  
(continued...)

To seek Matrix Benefits, a claimant must first submit a completed Green Form to the Trust. The Green Form consists of three parts. The claimant or the claimant's representative completes Part I of the Green Form. Part II is completed by the claimant's attesting physician, who must answer a series of questions concerning the claimant's medical condition that correlate to the Matrix criteria set forth in the Settlement Agreement. Finally, claimant's attorney must complete Part III if claimant is represented.

In May, 2011, claimant submitted a completed Green Form to the Trust signed by her attesting physician, Allan J. Stahl, M.D., F.A.C.C., F.A.C.P. Based on an echocardiogram dated December 16, 2010,<sup>3</sup> Dr. Stahl attested in Part II of claimant's Green Form that Ms. Glaser suffered from severe mitral regurgitation and had surgery to repair or replace the aortic and/or mitral valve(s) following the use of Pondimin® and/or

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2. (...continued)

serious VHD who took the drugs for 61 days or longer and who did not have any of the alternative causes of VHD that made the B matrices applicable. In contrast, Matrix B-1 outlines the compensation available to Diet Drug Recipients with serious VHD who were registered as having only mild mitral regurgitation by the close of the Screening Period or who took the drugs for 60 days or less or who had factors that would make it difficult for them to prove that their VHD was caused solely by the use of these Diet Drugs.

3. Because claimant's December 16, 2010 echocardiogram was performed after the end of the Screening Period, claimant relied on an echocardiogram dated March 13, 2002 to establish her eligibility to Matrix Benefits.

Redux™.<sup>4</sup> Based on such findings, claimant would be entitled to Matrix A-1, Level III benefits in the amount of \$800,618.<sup>5</sup>

Dr. Stahl also attested in claimant's Green Form that Ms. Glaser did not suffer from mitral annular calcification. Under the Settlement Agreement, the presence of mitral annular calcification requires the payment of reduced Matrix Benefits. See Settlement Agreement § IV.B.2.d.(2)(c)ii)d). As the Trust does not contest Ms. Glaser's entitlement to Level III benefits, the only issue before us is whether claimant is entitled to payment on Matrix A-1 or Matrix B-1.

In July, 2011, the Trust forwarded the claim for review by Alan J. Bier, M.D., F.A.C.P., F.A.C.C., F.A.S.E., one of its auditing cardiologists. In audit, Dr. Bier concluded that there was no reasonable medical basis for Dr. Stahl's finding that claimant did not have mitral annular calcification. In support of this conclusion, Dr. Bier explained, "There is clear mitral annular calcification on the [December 16, 2010] echo[cardiogram]."

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4. Dr. Stahl also attested that claimant suffered from pulmonary hypertension secondary to moderate or greater mitral regurgitation, an abnormal left atrial dimension, a reduced ejection fraction in the range of 50% to 60%, and New York Heart Association Functional Class III symptoms. These conditions are not at issue in this claim.

5. Under the Settlement Agreement, a claimant is entitled to Level III benefits if he or she suffers from "left sided valvular heart disease requiring ... [s]urgery to repair or replace the aortic and/or mitral valve(s) following the use of Pondimin® and/or Redux™." See Settlement Agreement § IV.B.2.c.(3)(a).

Based on the auditing cardiologist's finding that claimant had mitral annular calcification, the Trust issued a post-audit determination that Ms. Glaser was entitled only to Matrix B-1, Level III benefits. Pursuant to the Rules for the Audit of Matrix Compensation Claims ("Audit Rules"), claimant contested this adverse determination.<sup>6</sup> In contest, claimant argued that Dr. Bier incorrectly concluded that she had mitral annular calcification. According to claimant, the report of her December 16, 2010 echocardiogram "makes no mention of calcification"; the report of her December 21, 2010 echocardiogram, which claimant contended is more accurate because it is a transesophageal echocardiogram, stated, "There is no calcification of the annulus"; and her post-operative pathology report stated, "No calcifications are identified." In addition, claimant submitted a letter from Dr. Stahl wherein he confirmed his earlier opinion that Ms. Glaser did not have mitral annular calcification. Specifically, Dr. Stahl stated, in pertinent part, that:

I believe the cardiologist who reviewed these records is incorrect. I looked carefully at the December 16<sup>th</sup> echo[cardiogram] before answering the Green Form question that there was no mitral

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6. Claims placed into audit on or before December 1, 2002 are governed by the Policies and Procedures for Audit and Disposition of Matrix Compensation Claims in Audit, as approved in Pretrial Order ("PTO") No. 2457 (May 31, 2002). Claims placed into audit after December 1, 2002 are governed by the Audit Rules, as approved in PTO No. 2807 (Mar. 26, 2003). There is no dispute that the Audit Rules contained in PTO No. 2807 apply to Ms. Glaser's claim.

annular calcification and that is still my opinion. Sometimes there may be what appears to be some calcium present on a mitral valve leaflet in an echocardiogram, but that is not the same as saying a patient has mitral valve calcification.

Also, I've reviewed the surgery records and it is very apparent that Ms. Glaser did not have annular calcification. A transesophageal echocardiogram (TEE) done just before surgery clearly states that there was no calcification of the annulus. A TEE would be more accurate on this than the 2-D echo[cardiogram] that I and the other cardiologist looked at. The pathology report from the surgery leaves no doubt about this. The pathologist found no calcifications on the mitral valve. I think this is conclusive, since the pathologist was viewing the valve itself, not an echocardiogram image.

Although not required to do so, the Trust forwarded the claim to the auditing cardiologist for a second review. Dr. Bier submitted a declaration in which he affirmed his previous conclusion that there was no reasonable medical basis for Dr. Stahl's finding that claimant did not have mitral annular calcification. Specifically, Dr. Bier stated, in pertinent part, that:

11. At Contest, I reviewed the entirety of the Claim file and Contest Materials, and again found that there is clear echocardiographic evidence of mitral annular calcification on both the 12/16/10 echocardiogram of attestation and Claimant's study dated 12/3/10. Based on my review, I confirm my finding at audit, that there is no reasonable medical basis for the Attesting Physician's representation that Claimant did not have mitral annular calcification.



12. At Contest, I also reviewed Dr. Stahl's letter, submitted at Contest. Dr. Stahl states that Claimant's 12/21/10 TEE and post-operative pathology report support a finding that Claimant did not have mitral annular calcification.
13. The TEE study was not submitted, however, the report of the 12/21/10 TEE includes mixed messages. It first states that the mitral valve is "structurally normal," then describes multiple abnormalities included [sic] fixed and retracted leaflets, and then states there is no calcification. (See December 21, 2010 Intraoperative TEE Report.)
14. Although the post-surgical pathology report states "[n]o calcifications are identified," the pathology report relates to inspection of the mitral valve leaflets only - the annulus was not removed. (See Surgical Pathology Report.)
15. Finally, the 12/3/10 echocardiogram report, signed by Dr. Stahl, clearly states, "There was mitral annular calcification." (See 12/3/10 Echocardiogram Report.) Ultimately, Claimant's 12/16/10 and 12/3/10 echocardiograms clearly showed mitral annular calcification, and there is no reasonable medical basis to conclude that Claimant did not have this condition.

The Trust then issued a final post-audit determination, again determining that Ms. Glaser was entitled only to Matrix B-1, Level III benefits. Claimant disputed this final determination and requested that the claim proceed to the show cause process established in the Settlement Agreement. See Settlement Agreement § VI.E.7.; PTO No. 2807, Audit Rule 18(c). The Trust then applied to the court for issuance of an Order to

show cause why Ms. Glaser's claim should be paid. On February 22, 2012, we issued an Order to show cause and referred the matter to the Special Master for further proceedings. See PTO No. 8823 (Feb. 22, 2012).

Once the matter was referred to the Special Master, the Trust submitted its statement of the case and supporting documentation. Claimant then served a response upon the Special Master. The Trust submitted a reply on July 16, 2012. Under the Audit Rules, it is within the Special Master's discretion to appoint a Technical Advisor<sup>7</sup> to review claims after the Trust and claimant have had the opportunity to develop the Show Cause Record. See Audit Rule 30. The Special Master assigned a Technical Advisor, Gary J. Vigilante, M.D., F.A.C.C., to review the documents submitted by the Trust and claimant and to prepare a report for the court. The Show Cause Record and Technical Advisor Report are now before the court for final determination. See id. Rule 35.

The issue presented for resolution of this claim is whether claimant has met her burden of proving that there is a reasonable medical basis for the attesting physician's finding

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7. A "[Technical] [A]dvisor's role is to act as a sounding board for the judge-helping the jurist to educate himself in the jargon and theory disclosed by the testimony and to think through the critical technical problems." Reilly v. United States, 863 F. 2d 149, 158 (1st Cir. 1988). In a case such as this, where conflicting expert opinions exist, it is within the discretion of the court to appoint a Technical Advisor to aid it in resolving technical issues. Id.

that she did not have mitral annular calcification. See id. Rule 24. Ultimately, if we determine that there is no reasonable medical basis for the answer in claimant's Green Form that is at issue, we must affirm the Trust's final determination and may grant such other relief as deemed appropriate. See id. Rule 38(a). If, on the other hand, we determine that there is a reasonable medical basis for the answer, we must enter an Order directing the Trust to pay the claim in accordance with the Settlement Agreement. See id. Rule 38(b).

In support of her claim, Ms. Glaser reasserts the arguments made in contest, namely, that her medical records, echocardiograms, and echocardiogram reports confirm she did not have mitral annular calcification. In addition, claimant submits another letter from Dr. Stahl and a declaration of Michael G. Wood, M.D., the physician who performed her mitral valve replacement surgery. In his letter, Dr. Stahl states, in pertinent part, that:

For the echo[cardiogram] which I did on 12/03/2010, although my Report mentioned [mitral annular calcification], I and many cardiologists use that as a generic term whenever there is any [calcium] in the area of the mitral valve. Often, as in this case, it is not critical where the [calcium] is actually located and the generic term is used. However, Ms. Glaser did not have a calcified annulus, despite my generic use of the term.

Dr. Wood states in his declaration, in pertinent part, that:

3. I have been asked by Ms. Glaser's attorney whether the patient had mitral annular calcification at the time of her



surgery. It is my opinion, within a reasonable degree of medical certainty, that she did not.

4. Just prior to the surgery, an intraoperative transesophageal echocardiogram (TEE) was done, as is normal for that procedure. As stated in the TEE Report, and which I confirmed by my independent interpretation, the TEE showed that the mitral valve was structurally abnormal, the annulus was not dilated, the anterior leaflet had good mobility, the posterior leaflet was fixed with no mobility, there was severe central mitral regurgitation, and there was no calcification of the annulus.

5. In addition to the TEE, I of course viewed the mitral valve and the mitral annulus during surgery. Nothing that I observed caused me to believe that there was any mitral annular calcification present.

6. I would also note that a two-dimensional echocardiogram done on 12/16/2010, five days prior to surgery, made no mention of any mitral annular calcification and, in any event, the pre-operative TEE would be more reliable in making that determination than a normal 2-D [echocardiogram].

In response, the Trust argues that claimant's submissions do not rebut Dr. Bier's specific finding of mitral annular calcification based on his review of Ms. Glaser's December 3, 2010 and December 16, 2010 echocardiograms.

The Technical Advisor, Dr. Vigilante, reviewed claimant's echocardiograms and concluded that there was no reasonable medical basis for the attesting physician's finding that Ms. Glaser did not have mitral annular calcification. Specifically, Dr. Vigilante stated, in pertinent part, that:

I reviewed the DVD of the Claimant's echocardiogram of attestation. The patient's

name was noted as well as date of December 16, 2010. There were 52 images/loops that were recorded in this study. This was an excellent quality study with the usual echocardiographic views obtained. The Nyquist limit and color gain were appropriate.

There were excellent views of the mitral apparatus in the parasternal long-axis, parasternal short-axis, apical four chamber, and apical two chamber views.... This study also demonstrated classic mitral annular calcification with significantly increased echoes and increased refractoriness of the echoes in the posterolateral mitral valve annulus. Loop 3 demonstrated calcification of the posterior mitral annulus in the parasternal long-axis view. Loop 16 demonstrated posterolateral calcification of the mitral annulus in the parasternal short-axis view. Loops 27 and 29 demonstrated calcification of the lateral mitral annulus in the apical four chamber view. Loop 44 demonstrated calcification of the posterior mitral annulus in the apical two chamber view....

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I also reviewed the DVD of the Claimant's echocardiogram of December 3, 2010.... There were 52 images/loops noted on this study. This study was virtually identical to the echocardiogram of attestation. That is, there was significant calcification of the posterolateral mitral annulus associated with doming of the anterior mitral leaflet and thickening of these leaflets as well as subvalvular apparatus consistent with rheumatic mitral valvular disease....

In response to the Technical Advisor Report, claimant argues that the Technical Advisor Report does not undermine her argument that a transesophageal echocardiogram is preferred to a transthoracic echocardiogram. As a result, claimant says, there

is a reasonable medical basis for Dr. Stahl's representation that she does not have mitral annular calcification.

After reviewing the entire show cause record, we find claimant's arguments are without merit. As noted previously, the Settlement Agreement provides that the presence of mitral annular calcification requires the payment of reduced Matrix Benefits. See Settlement Agreement § IV.B.2.d.(2)(c)ii)d).

The auditing cardiologist and the Technical Advisor each reviewed claimant's medical records, including her December 3, 2010 and December 16, 2010 echocardiograms, and concluded that there was no reasonable medical basis for Dr. Stahl's representation that claimant did not have mitral annular calcification based on her December 16, 2010 echocardiogram. In particular, Dr. Bier stated "Claimant's 12/16/10 and 12/3/10 echocardiograms clearly showed mitral annular calcification." Similarly, Dr. Vigilante concluded that claimant's December 3, 2010 echocardiogram demonstrated "significant calcification of the posterolateral mitral annulus" while her December 16, 2010 echocardiogram "demonstrated classic mitral annular calcification with significantly increased echoes and increased refractoriness of the echoes in the posterolateral mitral valve annulus."

Claimant contends that her medical records are sufficient to overcome these clear and unambiguous findings. We disagree. For example, the fact that the report of claimant's December 16, 2010 echocardiogram "made no mention of any mitral

annular calcification" does not mean mitral annular calcification was not present. This is particularly true in light of the express findings of the auditing cardiologist and Technical Advisor. In addition, while claimant's post-operative pathology report indicates that no calcifications were identified, claimant does not dispute that her mitral annulus was not submitted to the pathologist for review.

Moreover, although Dr. Wood states that he independently confirmed that claimant's December 21, 2010 transesophageal echocardiogram did not evidence mitral annular calcification, that study was not available for review by the auditing cardiologist or the Technical Advisor. In addition, Dr. Wood's statement that "[n]othing that [he] observed caused [him] to believe that there was any mitral annular calcification present" is not the same as a statement that claimant did not have mitral annular calcification. In any event, Dr. Wood's findings alone, in light of the clear and unambiguous evidence of mitral annular calcification contained in the studies that were available for review, is not sufficient.

For the foregoing reasons, we conclude that claimant has not met her burden of proving that there is a reasonable medical basis for finding that she did not have mitral annular calcification. Therefore, we will affirm the Trust's denial of Ms. Glaser's claim for Matrix A-1 benefits.